REMARKS

The final Action mailed October 26, 2006, has been carefully studied. The claims in the application remain as claims 3-5 and 8, with claim 3 being proposed to be amended above as suggested by the examiner in the final action. Applicants' claims not only define patentable subject matter over the prior art (all the prior art rejections have been withdrawn), but also meet all other statutory requirements, and therefore the claims should be allowed. Favorable consideration and early formal allowance are both respectfully requested.

The prior art rejections having been withdrawn, applicants understand that applicants' claims are deemed by the PTO to define novel and unobvious subject matter under Sections 102 and 103.

Claims 3-5 and 8 have been rejected under the first paragraph of Section 112 as failing to comply with the enablement requirement. The rejection is respectfully traversed for the reasons of record.

Nevertheless, the examiner has helpfully suggested a way to overcome this rejection, the final action stating as follows in the top paragraph on page 4:

> Amending the claim to recite **a method of treatment of renal failure-associated metabolic bone disease** comprising administering an effective amount of erythropoietin for said treatment to a patient with renal failure-associated metabolic bone disease would obviate the instant rejection.

As this was applicants' intent in any event in view of what is clearly stated in the last line of claim 3, the amendment adds no limitation to applicants' claims, in applicants' view.

Withdrawal of the rejection is in order and is respectfully requested.

Claim 5 has been rejected under the first paragraph of Section 112 as failing to meet the written description requirement. This rejection is respectfully traversed.

With respect, this rejection makes no sense to applicants. The claims, i.e. both claims 3 and 5, specify that the patient to whom the treatment is administered is a patient "with said renal failure-associated metabolic bone disease." That means that all the species of metabolic bone disease which are set forth in claim 5 **must absolutely be** "renal failure-associated" metabolic bone diseases, i.e. the recited osteodystrophy and the recited osteoporosis must by definition be "renal failure-associated" metabolic bone

diseases. All this is entirely consistent with applicants' specification.

Does the examiner doubt that there is such a thing as renal failure-associated osteoporosis? Applicants' specification states as follows at page 6, line 17-21:

> Diseases, for which EPO of the present invention is indicated, are bone diseases showing impairments in bone metabolism, including, for example, renal failure-associated osteodystrophy, marble bone disease, diabetic nephropathy, and osteoporosis.

The modifier "renal failure-associated" applies to all the species, and applicants respectfully submit that it is unjustified for the examiner to interpret the language of applicants' specification in a narrower way than is intended and properly interpreted, **particularly** when there is such a substantial emphasis in applicants' specification throughout on the basis of renal failure-associate disease. In this regard, please note page 4, lines 17-20 which set forth an object of the present invention as relating to the "treatment of impaired bone metabolism **in a patient with renal failure**" (emphasis added).

Also please see page 6, lines 5, 6, 11, 12, etc. As noted above, the treatment provided by the present invention

concerns the treatment of metabolic bone disorders that are renal failure-associated, and that of course includes renal failure-associated osteoporosis.

Applicants respectfully note, as stated in the penultimate paragraph of MPEP 2163.02, that the "subject matter of the claim need not be described literally (i.e., using the same terms (or *in haec verba)* in order for the disclosure to satisfy the description requirement." Also please see MPEP 2163.07.

Further in this regard, applicants respectfully note that the initial burden is on the PTO, noting MPEP 2163.04, the last sentence of which states as follows:

> The examiner has the initial burden of presenting by **a preponderance of evidence** why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. [citation omitted]

It should be abundantly clear to anyone skilled in applicants' art that an application which is directed to the treatment of impaired bone metabolism in a patient with renal failure, which mentions osteoporosis as a species, clearly describes as one species of the invention the treatment of renal failure-associated osteoporosis.

Withdrawal of the rejection is in order and is respectfully requested.

Claims 3-5 and 8 have been rejected under the second paragraph of Section 112. This rejection is respectfully traversed.

As understood, this rejection is basically a repetition of the enablement rejection, but based on what the examiner considers is confusion in the claim, and therefore a defect under the second paragraph of Section 112. Applicants respectfully disagree, and therefore traverse the rejection.

Applicants believe that recitation of the wording "renal failure-associated" in the claim preamble is unnecessary as the body of the claim following the transitional term "comprising" is what controls. Nevertheless, the amendment helpfully suggested by the examiner should obviate this rejection, and such an amendment is proposed above.

Withdrawal of the rejection is in order and is respectfully requested.

All issues raised in the final action are believed to have been fully addressed above in such a way as to lead to formal allowance. Accordingly, applicants respectfully

request favorable consideration, entry of the amendment presented above, and early formal allowance.

Respectfully submitted,

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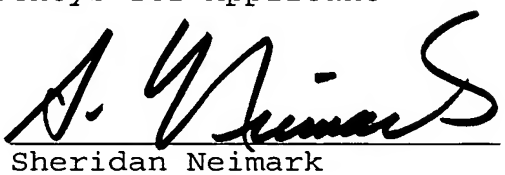
By 
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